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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,181	02/12/2002	Judith Aronhime	1662/56002	4579

26646 7590 07/22/2005

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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 07/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/074,181

Applicant(s)

ARONHIME ET AL.

Examiner

Brenda L. Coleman

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-11,13-20,22-33 and 35-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2-11,13-20,22-32,35,36,38-44 and 46-57 is/are allowed.
- 6) ☒ Claim(s) 33,58-64 and 68-72 is/are rejected.
- 7) ☒ Claim(s) 37,45 and 65-67 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 2-11, 13-20, 22-33 and 35--72 are pending in the application.

This action is in response to applicants' amendment filed May 9, 2005. Claims 2, 5, 7, 8, 11, 13-16, 20, 22-24, 32, 35, 36, 46, 47, 49, 50, 52-54 and 56-59 have been amended and claims 1, 12, 21 and 34 have been canceled.

Response to Amendment

Applicant's amendments filed May 9, 2005 have been fully considered with the following effect:

1. With regards to the 35 U.S.C. § 112, first paragraph rejection of claims 68, 69, 71 and 72 labeled paragraph 1 of the last office action, the applicants' arguments have been fully considered, however they were not found persuasive. Applicants' stated that one of the factors to consider for enablement is the level of one of ordinary skill in the art. In support of this aspect they cited the *Physician's Desk Reference*, which illustrates that the level of skill in the field of treating epilepsy with oxcarbazepine is sufficiently high. The applicants also state with respect to the absence of screening protocols or working examples that the PDR discloses numerous clinical studies performed to determine the effectiveness of oxcarbazepine. It is noted that the information and instruction in the PDR for the use of oxcarbazepine in the treatment of epilepsy is vast. However, the claim language of claim 68 is such that the method of preventing or reducing the severity of seizures encompasses more than just epilepsy. Additionally, not all diseases and/or disorders claimed herein are treatable, let alone preventable.

Claims 68, 69, 71 and 72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record and stated above.

2. The applicants' amendments and arguments are sufficient to overcome the 35 USC § 112, second paragraph rejections labeled paragraph 2 of the last office action, which are hereby **withdrawn**.

3. With regards to the 35 U.S.C. § 102(b), anticipation rejection of claims 1, 12, 21, 58-64, 68, 69 and 71 of the last office action, the applicants' arguments have been fully considered, however they were not found persuasive. Applicants' stated that claims 58-64, 68, 69 and 71 encompass pharmaceutical compositions comprising oxcarbazepine forms of the invention and that pharmaceutical compositions of the invention comprise the oxcarbazepine polymorphs in solid form where their crystalline structures are retained. However, the applicants are not specifically claiming solid pharmaceutical compositions, but pharmaceutical compositions in general.

Claims 58-64, 68, 69 and 71 are rejected under 35 U.S.C. 102(b) as being anticipated by SCHINDLER, U.S. Patent No. 3,716,640, for reasons of record and stated above.

4. With regards to the 35 U.S.C. § 102(b), anticipation rejection of claims 1, 12, 21, 33, 58-64 and 68-71 of the last office action, the applicants' arguments have been fully

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considered, however they were not found persuasive. Applicants' stated that claims 58-64 and 68-71 encompass pharmaceutical compositions comprising oxcarbazepine forms of the invention and that pharmaceutical compositions of the invention comprise the oxcarbazepine polymorphs in solid form where their crystalline structures are retained. However, the applicants are not specifically claiming solid pharmaceutical compositions, but pharmaceutical compositions in general.

Claims 33, 58-64 and 68-71 are rejected under 35 U.S.C. 102(b) as being anticipated by BOIREAU et al., U.S. Patent No. 5,658,900, for reasons of record and stated above.

Claim Objections

5. Claims 37, 45 and 65-67 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Allowable Subject Matter

6. Claims 2-11, 13-20, 22-32, 35, 36, 38-44 and 46-57 are allowed. None of the prior art of record or a search in the pertinent art area teaches the compounds or the process of preparing the crystalline oxcarbazepines as claimed herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Brenda Coleman
Primary Examiner Art Unit 1624
July 19, 2005